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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,957	04/03/2007	Brian Steer	D1150-7N	1684

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VERENIUM CORPORATION  
Intellectual Property Department  
P.O. Box 910550  
SAN DIEGO, CA 92191-0550

EXAMINER
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MEAH, MOHAMMAD Y

ART UNIT	PAPER NUMBER
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1652

NOTIFICATION DATE	DELIVERY MODE
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05/11/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Ip@verenum.com  
lynn.linkowski@verenum.com  
jennifer.risser@verenum.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,957	<b>Applicant(s)</b> STEER ET AL.	
	<b>Examiner</b> MD. YOUNUS MEAH	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38,60,91,92,95,96,98,162,175,177,180,187 and 200-2002 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/14/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/5/10, 7/29/09, 9/30/08, 3/29/06</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1, 27, 31, 34, 38 to 42, 45, 48, 50, 52, 54, 56, 57, 59, 60, 91, 92, 95, 96, 98, 100, 102 to 104, 106, 108 to 112, 126, 131,141,146, 162 to 164, 173,175 to 178, 180, 181, 187, 189, 197, 199 to 206, 209 to 211,213,221 and 222 .

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1, 27, 31, 34, 39-42, 45, 48, 50, 52, 54, 56, 57, 59, 100, 102 to 104, 106, 108 to 112, 126, 131,141,146, 163 to 164, 173,176, 178, 181, 189, 197, 199, 203- 206, 209 to 211,213, and 222 .

### **DETAILED ACTION**

Claims 1, 27, 31, 34, 38 to 42, 45, 48, 50, 52, 54, 56, 57, 59, 60, 91, 92, 95, 96, 98, 100, 102 to 104, 106, 108 to 112, 126, 131,141,146, 162 to 164, 173,175 to 178, 180, 181, 187, 189, 197, 199 to 206, 209 to 211,213,221 and 222 are pending. With preliminary amendment of this application, the applicant, on date 2/5/2010 elected with traverse Group 278 (claims 38, 60, 91-92, 95-96, 98, 162, 175, 177, 180, 187, 200-2002) for examination. Applicant canceled claims 116, 120-122 and added new claims 221-222. New claim 221 belongs to elected group and therefore will be examined; however claim 222 belongs to non-elected group and therefore is withdrawn. Claims 1, 27, 31, 34, 39-42, 45, 48, 50, 52, 54, 56, 57, 59, 100, 102 to 104, 106, 108 to 112, 126, 131,141,146, 163 to 164, 173,176, 178, 181, 189, 197, 199, 203- 206, 209 to 211,213, and 222 belonging groups 1-277 and 279-5438 of election/restriction-office action of date 09/17/2009 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups. Claims 38, 60, 91-92, 95-96, 98, 162, 175, 177, 180, 187, 200-202 and 221 are for examination.

Applicant argue that if elected product claims of group 238 are found allowable all the process claims that use the product should be rejoined. Applicants' argument is considered. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

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Applicants further argue that the claims are linked by a special technical feature because Poole et al. do not disclose the technical feature of the claims which applicant argue that is 80% sequence identity to SEQ ID NO: 38. Applicants' argument is considered but found unpersuasive. Claim 60 comprise any polypeptide having at least one conservative amino acid residue substitution from the polypeptide which is 80% sequence identical to SEQ ID NO: 38 and claim 38 comprise active fragment of SEQ ID NO: 38. Poole et al. Glucanase which is 62% identical to applicants SEQ ID NO: 2 comprise active fragment of applicants polypeptide of SEQ ID NO: 38; therefore Poole et al disclose the special technical feature of claim 38 or claim 60. Further evidence that the claims lack special technical feature is found in rejection heading under U.S.C.102 below. The restriction is made final.

### ***Priority***

This application is a 371 of PCT/US04/21492, filed 07/02/2004 which claims benefit of 60/484725 filed 07/02/2003.

### ***Specification Objection***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code at paragraphs 0241 and 0716. See MPEP § 608.01.

### ***Objection***

Claim 98 is objected for comprising non-elected subject matter. Appropriate correction is required.

Claim 38 is objected for depending on non-elected claim 34. Appropriate correction is required.

Claim 98 is objected for depending on non-elected claim 1. Appropriate correction is required.

Claim 60 is objected for depending on non-elected claim 1. Appropriate correction is required.

Claim 221 is objected for depending on non-elected claim 1. Appropriate correction is required.

***Claim Rejections 35 U.S.C 112 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 92 and 95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 92 and 95 are confusing in the recitation of "A heterodimer" or "homodimer" as the remainder of the claims suggest that applicants intend these claims to recite fusion proteins (i.e., covalently bound proteins) of the polypeptide of Claim 60 yet the terms heterodimer and homodimer in the art would mean non-covalently bound association of two polypeptide chains (either two different chains or two identical chains respectively). It is suggested that the claims be amended to recite a fusion polypeptide.

***Claim Rejections, 35 U.S.C 112 1<sup>st</sup> Paragraph***

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38, 60, 91-92, 95-96, 98, 162, 175, 177, 180, 187, 200-202 and 221 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 38, 60, 91-92, 95-96, 98, 162, 175, 177, 180, 187, 200-202 and 221 (depend on claim 60) is directed to any polypeptide which is (1) at least 80% sequence identical to SEQ ID NO: 38, (2) encoded by polynucleotide which comprises any fragment of SEQ ID NO: 37, (3) any polypeptide having any number of conservative amino acid modifications within SEQ ID NO: 38, (4) a protein encoded by a polynucleotide that hybridizes under any conditions to the polynucleotide of SEQ ID NO: 37 wherein said polypeptide having glucanase activity, signal sequence of said polypeptide and comprising various compositions comprising said polypeptide. As discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed

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correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The specification teaches a few polypeptides having the amino acid sequences of SEQ ID NOs: 2, 6, 8, 10, 12, 14, 16 -----or 518 having glucanase activity. However, the specification fails to describe any other representative species of the genus of polypeptides required to practice the homology claimed by sufficient identifying characteristics or properties to show that applicant was in possession of the recited genus.

The structural features recited in the claims are either minimal or essentially non-existent because claim requires any number of conservative amino acid modification of SEQ ID NO; 38. There is no art-recognized structure/function correlation which would allow one ordinary skill in the art to distinguish from all the possible polypeptides having the recited structural features, which ones have the desired activity. Therefore one of skill in the art would not recognize from the disclosure that applicants' were in possession of the claimed invention.

Applicants' are referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).



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Claims 38, 60, 91-92, 95-96, 98, 162, 175, 177, 180, 187, 200-202 and 221 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for glucanase polypeptide of the amino acid sequences of SEQ ID NO: 38, does not reasonably provide enablement for any polypeptide which is (1) at least 80%,...99% sequence identical to SEQ ID NO: 38, (2) encoded by polynucleotide which comprises any fragment of SEQ ID NO: 37, (3) any polypeptide having any number of conservative amino acid modifications within SEQ ID NO: 38, (4) a protein encoded by a polynucleotide that hybridizes under any conditions to the polynucleotide of SEQ ID NO: 37 wherein said polypeptide having glucanase activity, signal sequence of said polypeptide and comprising various compositions comprising said polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breath of the claim(s).

Claims 38, 60, 91-92, 95-96, 98, 162, 175, 177, 180, 187, 200-202 and 221 encompass any polypeptide which is (1) at least 80% sequence identical to SEQ ID NO:

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38, (2) encoded by polynucleotide which comprises any fragment of SEQ ID NO: 37, (3) any polypeptide having any number of conservative amino acid modifications within SEQ ID NO: 38, (4) a protein encoded by a polynucleotide that hybridizes under any conditions to the polynucleotide of SEQ ID NO: 37 wherein said polypeptide has glucanase activity. However, neither the specification nor the state of the art at the time of the invention provided the necessary guidance for making and/or isolating a polynucleotide encoding a protein having the recited activity as recited in the claims. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the large number proteins of unknown structure encompassed by the claims.

Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. The reference of Chica et al. (Curr Opin Biotechnol. 2005 Aug;16(4):378-84; PTO 892) teaches that the complexity of the structure/function relationship in enzymes has proven to be the factor limiting the general application of rational enzyme modification and design, where rational enzyme modification and design requires in-depth understanding of structure/function relationships.

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The positions within a protein's amino acid sequence where modifications can be made with a reasonable expectation of success in obtaining a polypeptide having the desired glucanase activity are limited in any protein and the result of such modifications is highly unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g., multiple substitutions, deletions, additions, and combinations thereof.

Methods for isolating or generating variants and mutants using random mutagenesis techniques were known in the art. However, neither the specification nor the state of the art at the time of the invention provided the necessary guidance for altering the amino acid sequence of SEQ ID NO: 38 with an expectation of obtaining a polypeptide having the same glucanase activity. At the time of the invention, there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the same desired biological activity. For example, the reference of Witkowski et al. (Biochemistry. 1999 Sep 7; 38(36): 11643-50) teaches that only a single amino acid substitution results in conversion of the activity of a polypeptide to a second, distinct activity (see e.g., Table 1, page 11647). In addition, the reference of Seffernick et al. (J Bacteriol. 2001 Apr; 183 (8): 2405-10) teaches that two proteins with 98% amino acid sequence identity were found to catalyze different reactions, where one protein has melamine deaminase activity and the other protein has atrazine chlorohydrolase activity (see Fig.3, page 2408; DISCUSSION section on page 2409).

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The specification does not support the full scope of the claimed method because the specification, does not establish: (A) regions of the protein structure which may be modified without effecting having glucanase activity; (B) the general tolerance of polypeptides having glucanase activity to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residue in a polypeptide having glucanase activity with an expectation of obtaining the desired biological function; (D) which are the structural features in the polypeptide of SEQ ID NO: 2 which should be present in any protein having the recited activity, and (E) sufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

In view of the amount of experimentation required to isolate/make all the proteins having glucanase activity required by the claimed method, the lack of guidance, lack of working examples, and unpredictability of the art in assigning function (i.e., glucanase activity) based solely on structural similarity, the claimed invention would require undue experimentation.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of all the polypeptides having glucanase activity encompassed by the claims is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

***Claim Rejection 35 U.S.C 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 38 and 60 are rejected under 35 U.S.C. 102 (e) as being anticipated by Adney et al (US 7,393,673, based on application filed on July 28, 2001).

Claims 38 and 60 are directed to a polypeptide which is encoded by a polynucleotide that hybridizes under any stringent conditions to a complement of polynucleotide of SEQ ID NO: 37 (via depending on claim 1, see claim 1e). A complement of polynucleotide of SEQ ID NO: 37 may comprise any length of nucleotide residues of SEQ ID NO: 37, which may comprise 3 or more nucleotides, for example. Therefore claims 38 and 60 are broadly interpreted comprising a polypeptide which is encoded by a polynucleotide fragment of any length that hybridizes under any conditions to a fragment of polynucleotide comprising any length of nucleotide residues of SEQ ID NO: 37 and therefore comprise a fragment of SEQ ID NO: 38 (SEQ ID NO: 37 encodes SEQ ID NO: 38) of any length.

Adney et al teach glucanase polypeptide of SEQ ID NO: 4 which is 13% sequence identical to applicants SEQ ID NO: 38 (see sequence alignment below) and also teach DNA encoding said polypeptide (column 3, lines 10-35). Adney et al DNA encoding SEQ ID NO: 4 would hybridize with any fragment or portion of applicants SEQ ID NO: 37 and also Adney et al glucanase polypeptide of SEQ ID NO: 4 which is 13%

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sequence identical to applicants SEQ ID NO: 38 is a fragment of applicants SEQ ID NO: 38. Therefore Adney et al. anticipate claims 38 and 60 of the instant application as interpreted.

**Sequence alignment for SEQ ID NO: 38 of the application with SEQ ID NO: 4 of  
US 7,393,673.**

## RESULT 9

US-09-917-384-4

```
; Sequence 4, Application US/09917384
; Publication No. US20030096342A1
; GENERAL INFORMATION:
; APPLICANT: DING, SHI-YOU
; APPLICANT: ADNEY, WILLIAM S.
; APPLICANT: VINZANT, TODD B.
; APPLICANT: DECKER, STEPHEN R.
; APPLICANT: HIMMEL, MICHAEL E.
; TITLE OF INVENTION: THERMAL TOLERANT CELLULASE FROM ACIDOTHERMUS
; TITLE OF INVENTION: CELLULOLYTICUS
; FILE REFERENCE: 40170.6US01
; CURRENT APPLICATION NUMBER: US/09/917,384
; CURRENT FILING DATE: 2001-07-28
; NUMBER OF SEQ ID NOS: 14
; SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 4
; LENGTH: 423
; TYPE: PRT
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Description of Artificial Sequence: Segment of
; OTHER INFORMATION: GuxA
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US-09-917-384-4

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Query Match          13.2%; Score 814; DB 3; Length 423;
Best Local Similarity 49.4%;
Matches 164; Conservative 56; Mismatches 100; Indels 12; Gaps
7;
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Qy      803 THLDNPFVGATFYRNVYVASVNAAADSQT-GTLAAQMRLVANYPTFVWLDSIDAVNGTN
861
      ||:|:|: |||: | : | : | :|| |||:|:|: | | |:| | |:| |
Db      2 THVDNPHYAGATFFVNPYWAQEVQSEANQTNATLAAKMRVVSTYSTAVWMDRIAAINGVN 61

Qy      862 GYPRSLAGHLNAAITQ----GANAIGIVVYDLPNRDCSALASNGELLIAQNLNRYKTEY
917
      | | | :|:|:|:| | | | | | | | | | | | | | | | | | | | | |
Db      62 GGP-GLTTYLDAALSQQQGTTPVEIVYDLPGRDCAALASNGELPATAAGLQTYETQY
120
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Qy 918 IDAIYNTISQPQYSNLRIIMVIEPDSLPLNLTNLSFAKCSEAQSTGAYVQGVQYALGTLR  
977  
|| | : :| | :||:|||| : ||||| |||:| | | : | ||:|||| |  
Db 121 IDPIASILSNPKYSSLRIVTIIIEPDSLPLNAVTNMSIQAC--ATAVPYEQGIEYALTKLH  
178

Qy 978 SLNNTYAYIDVAHAAWLGWPSNFTPFVNLLKTVGTGIPGGNSKVDGFISNTANYNPVDEP  
1037  
: : | | |:| ||: ||||:| : :| : : | | | :||:||||| |: ||  
Db 179 AIPNVYIYMDAAHSGWLGWPNNASGYVQEVQKVLNASIGVNG-IDGFVTNTANYTPLKEP  
237

Qy 1038 FMDANTMVGGNPVRSLOGWYDWNDYIDEQPYILALRTALTGTDAYPTSVGVIIDTSRNG  
1097  
|| | ||| || | :| || ||| | : | : | :||:||||| |||  
Db 238 FMTATQQVGGQPVES-ANFYQWNPDIIDEADYAVDLYSRLVAA--GFPSSIGMLIDTLRNG  
294

Qy 1098 WGGTNRPTAASTSTVLSTFVME SRIDKRIHKG 1129  
||| | || ||:| :||| :|:| | | :|  
Db 295 WGGPNEPTGPSTATDVNTFVNQSKIDLRQHRG 326

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah  
Examiner, Art Unit 1652

/Tekchand Saidha/  
Primary Examiner, Art Unit 1652